



FORE News

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Medical Director Update

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Remember...
 Due to recent advances, Osteoporosis can now be treated. Talk to your physician about having a bone density test. It is a painless method of establishing your risk of fracture & likelihood of developing osteoporosis.

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Bone Density Test Can Predict Fractures Over Twenty-Five Years

We are often asked 'How good are these p-DEXA tests?' What physicians and patients are asking really is, whether these tests can predict fractures and over how long a period of time.

In the field of osteoporosis, there is great controversy over whether there is enough data to make predictions over the next five years (referred to as "current fracture risk") or well into the future (referred to as "future fracture risk"). A recent study entitled 'A Single Bone Density Measurement Can Predict Fractures Over 25 Years' (Duppe et. al., *Calcified Tissue Int.* 60: 171- 174, 1997) looked at this issue. A group of 1,076 women (aged 20 to 78 years) had their forearm bone density measured from 1970 to 1975. Fracture information was collected on the 410 women that were still alive at the end of the study in 1994. The data found that there were 213 osteoporotic fractures (wrist, hip, shoulder and spine) recorded after this interval of 20 to 25 years. Analysis of this data showed that there was a 1.66 fold increase in hip fracture risk for each reduction of a standard deviation in the forearm bone density from 25 years earlier. These results clearly indicate that the risk of each type of fracture, including hip fracture, is, in fact, able to be significantly predicted by a single bone density test at the forearm on a 25 year perspective.

Community Awareness Bone Density Testing Program: 18 Months Experience

Risa Kagan, MD, FORE's Co-Medical Director, presented the above-titled poster at the Fourth Annual Scientific Meeting of the International Society of Clinical Densitometry held in Orlando, FL on January 15-18, 1998. This study gave physicians an opportunity to review the data from FORE's internationally acclaimed Community Awareness Bone Density Testing Program. The poster emphasized both the growth of the program from 10 Longs pharmacies in June, 1996 to 69 stores and 40 non-pharmacy sites such as clubs, gyms, meetings and work-sites by December, 1997 as well as the simultaneous physician and community education programs that have made FORE's program unique. Over the time interval of the study, FORE performed nearly 2,100 central bone density tests at our locations in Oakland and San Ramon, while performing over 10,000 pDEXA tests. This confirms the finding that accessibility to testing facilitates the evaluation of many times the number of individuals than the smaller numbers of patients who are referred to testing centers by their physician. Overall, 41% of all individuals tested were found to be at increased risk of future fracture, by virtue of low bone mass. Most of these individuals will need further medical evaluation by their physician to decide if any treatment is indicated. Compared to programs that identify patients at risk for other diseases, ie. high cholesterol, cancer, etc.; where the identification of a patient at risk occurs in a much smaller percentage of cases, a finding of over 40% of patients at risk of fracture is both rewarding and clearly indicative of the continued need for this valuable service.

More Attention Should Be Paid To Childhood Fractures

For a number of years, based on an article by Chan et. al. 'Bone Mineral Status in Childhood Accidental Fractures,' (Am J Dis Child, 1984), childhood fractures were thought to indicate that the child was at risk for underlying bone problems. In no small part, this was due to the fact that while all children fall in the school yard, not all fracture. Now, a new study by Goulding et. al. "Bone Mineral Density in Girls with Forearm Fractures" (Journal of Bone and Mineral Research, January, 1998) has re-examined this issue using more modern techniques. All girls aged 3 to 15 years in Dunedin, Scotland, with wrist fractures (n=123) were asked to participate in a study to correlate bone mass measurement with fracture. Analysis of the 100 Caucasian girls who participated in the study found that all had suffered their forearm fracture at play. The degree of trauma was slight in 60 cases, moderate in 38 cases and severe in 2 cases. Bone density tests were performed on the spine, hip and forearm, and data on lean body mass and total body bone mineral content were also gathered. The most important conclusion to emerge from the study was that low bone density is more common throughout the skeleton in young girls with recent forearm fractures, than in controls who have never fractured.

This is the first study to show that the girls with fractures have lower hip and spine bone density than controls. Furthermore, girls with fractures between the ages of 3 to 7 had a lesser calcium intake than controls. Thus, parents, pediatricians and orthopedists need to be aware of these findings and pay attention to diet, exercise and

other bone health issues in young girls. Whether these girls are at higher risk for fracture after the menopause will still need to be determined.

Guidelines of Care---Revisited

As the move to identify clinical pathways in medicine becomes broadly accepted, the existence of guidelines and standards of care to assist the physician are critical. Thus, the Guidelines of Care on Osteoporosis for Primary Care Physicians, developed and published by FORE, is a useful and state-of-the-art document outlining protocols for patient identification, testing and treatment options for children, men and women. In an effort to ensure the ongoing utility and accuracy of these Guidelines, the Medical Advisory Sub-Committee on Guidelines met again in mid-February to review current literature and update the Guidelines in accordance with new information, Specific areas such as bone density testing including single site measurement issues and bisphosphonates, including the new alendronate (Fosamax) data, have been expanded and changes have been made to conform to current knowledge levels. New drugs such as raloxifene (Evista) have also been added. Copies of the revised Guidelines will be available in the FORE Office after May 1 st , 1998. The Guidelines will be distributed at no charge for the first copy.

EVISTA

A new selective estrogen receptor modulator (SERM) has been approved by the FDA and is now available by prescription in your pharmacy. Evista (raloxifene hydrochloride) has been approved for the prevention of osteoporosis after menopause. Evista acts like estrogen on the bones by reducing bone resorption (loss) and decreasing overall bone turnover. It is important to note that it is not approved or recommended for the treatment of osteoporosis because it builds bone to a lesser extent than estrogen. Currently, it is not known whether Evista prevents fractures. The effects of Evista on bone mass density (**BMD**) in post menopausal women were evaluated in three large randomized, placebo-controlled, double-blind osteoporosis prevention trials of over 1700 women. All of these women received calcium supplementation and were approximately 5 years post menopausal. They all had normal or **osteopenic** BMD. Evista increased BMD in the total body, hip and spine by approximately 1.3% - 2.4%. This was seen at 12 months and was maintained at 24 months. The calcium supplemented placebo group lost 1% of BMD at 24 months.

Clinical data indicate that Evista has estrogen-like effects on lipid metabolism. It decreases total cholesterol and LDL-cholesterol, but appears to have no effect on HDL-cholesterol or triglycerides, Unlike estrogens, Evista does not stimulate the breast or the uterus; therefore, women are free of breast tenderness or vaginal bleeding.

Patients taking Evista had a higher occurrence of hot flashes compared to the placebo group, but it was unusual for patients to develop these symptoms after the first 6 months of therapy. Evista is another new alternative to estrogen and low dose Fosamax (alendronate) for the prevention of osteoporosis. However, there is a small risk of phlebitis (similar to that for estrogen) and raloxifene's effect is not yet known

on cognitive function, where estrogen seems to have an important effect. It is an ideal alternative for a woman who is at risk for osteoporosis or heart disease; but cannot, or chooses not to, take traditional hormone replacement therapy.

FORE Sponsors Programs on Advances in Osteoporosis

The month of April is traditionally a very active one for osteoporosis education and 1998 will be no exception. On Wednesday, April 22, James Simon, MD will be addressing the Northern California Bone and Mineral Club on 'Menopause, Osteoporosis, and Selective Estrogen Receptor Modulators' at the World Trade Club in San Francisco. On Friday, April 24th FORE will be sponsoring the 3rd Annual Conference for Primary Care Physicians entitled "Advances in the Evaluation and Treatment of Osteoporosis" to be held at The Lakeview Club in Oakland. Several nationally-recognized speakers will be highlighting this meeting, including Dr. Simon, Dr. Christine Simonelli from the University of Minnesota, Dr. Diane Schneider from the University of California, San Diego and Dr. Laura Bachrach from Stanford University. Additionally, on Saturday, April 25th, FORE will be hosting the 2nd Annual Conference for Allied Health Professionals, which last year was attended by over 200 nurses, physical and occupational therapists and dietitians. This year's meeting highlights include Dr. Deborah Gold on the psychosocial issues facing the patient with osteoporosis, Dr. Christine Snow and Wendy **Katzman**, PT on the role of exercise and rehabilitation, Dr. Bachrach with the latest calcium information and Dr. Simon with a general overview of osteoporosis and current treatment options. For further information or registration materials for any of these programs, please call the FORE office.

Low Dose Esterified Estrogen Therapy

A very exciting article was published in the Archives of Internal Medicine, Dec., 1997, titled 'Low Dose Esterified Estrogen Therapy.' This study received a lot of media and scientific attention prompting many phone calls from interested patients. Members of the **Estratab/Osteoporosis** Study Group studied the effects of three doses of unopposed esterified estrogens (Estratab) on BMD, lipids, and endometrial tissue. These effects were monitored along with changes in blood estradiol levels. In the past, prospective studies have shown that doses equivalent to conjugated equine estrogens of 0.625 mg/day or higher are needed to produce a significant increase in BMD of the spine. 406 post menopausal women were given calcium and were randomly assigned to receive esterified estrogens (0.3 mg/day, or 1.25 mg/day) or placebo for 24 months. On the average, all doses of esterified estrogens produced significant increases in BMD of the lumbar spine, total hip and whole body compared to the placebo group. All three doses also had a dose-related beneficial effect on lipids as well. In contrast to the two higher doses, 0.3 mg/day of esterified estrogens had the same incidence of endometrial hyperplasia as in of the placebo group.

These results suggest that the use of low-dose estrogens (0.3 mg/day) may be sufficient to prevent post menopausal bone loss and may also reduce one's risk of cardiovascular disease. For many women this is a more comfortable dose, since there appears to be less breast tenderness, bleeding, and bloating with lower doses of

estrogen. Women who are anxious about the use of long term hormone replacement therapy may find that this lower dose can enhance compliance. One limitation of this study was although the group treated with low dose estrogen did well, the article does not report on the actual number of women who may have lost bone at this dose.

